APPENDIX A

Relator's Allegations	Prior Public Disclosure
SAC ¶ 84(a), (d): Defendants misled the USPTO by comparing Zytiga's market share in the chemo-naïve market to that of Xtandi because Xtandi "had not been approved by the FDA for chemo-naïve mCRPC patients" until September 2014 and Xtandi is Zytiga's principal competitor in the mCRPC market. The time periods for which "market share" data was shown on slide 12 of Defendants' patent submission was misleading.	"The U.S. Food and Drug Administration today approved Xtandi (enzalutamide) to treat men with late-stage (metastatic) castration-resistant prostate cancer that has spread or recurred, even with medical or surgical therapy to minimize testosterone." RJN, Ex. C at 41 (June 4, 2013 Submission for '340 Application). "Approved for prostate cancer patients previously treated with docetaxel, another anti-cancer treatment, Xtandi was reviewed under the FDA's priority review program ... Xtandi received FDA approval three months ahead of the product's prescription drug user fee goal date of Nov. 22, 2012." *Id.* Chart on Slide 12 of "Overall US Patient Share Continues to Grow" clearly shows Chemo Refractory and Chemo Naïve markets as separate sub-markets in which Zytiga is competing for market share. Dates of market share are clearly shown on the slide, and elsewhere in the submission dates and scope of approval for Xtandi are provided. *Id.* at 58.
	"During prosecution, Applicants alleged that Zytiga's market shares of 70% in the 'post-chemo' mCRPC market prior to the launch of Xtandi and 57% after the launch of Xtandi indicated that the claimed invention was a commercial success [citing slide 12]. Even assuming that the market definition Applicants used is accurate (and it is not), this information is insufficient as a matter of law because it fails to show any nexus between the claimed combination and the commercial performance of Zytiga. In addition, as Dr. McDuff explains, evidence of Zytiga's purported market share in a market Applicants define as the 'post-chemo' mCRPC therapeutic market is deficient for a number of reasons. First, Applicants adduced no evidence that a market consisting only of 'post chemo' mCRPC patients is the appropriate relevant market. As Dr. McDuff explains in his declaration, this market definition is much too narrow. Using a market definition that includes all mCRPC patients immediately reduces Zytiga's market share substantially. Second, recent market data demonstrate a steep and continuous decline in Zytiga's market share post-Xtandi launch, and concurrent growth in Xtandi market share." RJN, Ex. D at 129-30 (Amerigen IPR Petition).
	Applicant's representation of Zytiga's market shares on slide 12 "was misleading and incomplete, and could not suffice as a basis for allowing the '438 patent because Zytiga was not an unexpected commercial success when viewed in the proper market context." RJN, Ex. E at 205 (Mylan IPR Petition).
	"The FDA has expanded the approval for enzalutamide (Xtandi) to include the treatment of men with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC), based on survival data from the phase III PREVAIL trial." RJN, Ex. T at 1 (journal article).
	"The FDA today approved enzalutamide for patients with metastatic castration-resistant prostate cancer that has spread or recurred, despite medical or surgical therapy to reduce testosterone. Approved for prostate cancer patients previously treated with docetaxel, enzalutamide (Xtandi, Medivation Inc.) was reviewed under the FDA's priority review program." RJN, Ex. U at 1 (journal article).
	"This new drug application provides for the use of Xtandi® (enzalutamide) Capsules for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel." RJN, Ex. QQ at 1 (FDA Xtandi NDA approval letter, available on FDA webpage (see RJN, Ex. PP)).
	"This new drug application for Xtandi (enzalutamide) Capsules was received on 5/22/12 and requests approval for the indication of "treatment of patients with castration-resistant prostate cancer who have received docetaxel." RJN, Ex. RR at 2 (Center for Drug Evaluation and Research Division Director Summary Review, available on FDA webpage (see RJN, Ex. PP)).

Relator's Allegations	Prior Public Disclosure
SAC ¶ 84(a): Defendants misrepresented Zytiga's share of the mCRPC market because "Xtandi's market share quickly surpassed Zytiga's market share shortly after Xtandi's FDA approval in the chemo-naïve submarket" and eventually overtook "Zytiga as the dominant drug for chemo-naïve mCRPC patients and for mCRPC patients overall."	"[R]ecent market data demonstrate a steep and continuous decline in Zytiga's market share post-Xtandi launch and concurrent growth in Xtandi market share ... this market shift is particularly notable in light of Applicants' argument during prosecution that Zytiga's continued commercial success after the introduction of Xtandi was further evidence of the commercial success of the invention." RJN, Ex. D at 129-30 (Amerigen IPR Petition).
	"Xtandi has taken Zytiga's market share." RJN, Ex. F at 292 (Wockhardt IPR Petition). "Competition from Xtandi has also resulted in (1) lowering of Zytiga's price, (2) industry expectations that Xtandi will become the premier treatment option, and (3) Janssen's investment in a competitor to Xtandi. This market shift is particularly notable in light of the applicants' argument during prosecution that Zytiga's continued commercial success after the introduction of Xtandi was further evidence of the commercial success of the invention." *Id.* at 292-93 .
	"With Zytiga facing generic competition and increased pressure from Xtandi, revenues from Johnson & Johnson's drug will begin falling." RJN, Ex. R at 1 (business article). "After the launch of Zytiga, J&J quickly took a leading share of the prostate cancer market. However, the launch of Xtandi in 2013 placed pressure on J&J. Other competitors were not approved for first-line treatment, and this significantly improved Zytiga's position. Zytiga has lost market share in the US to Xtandi while still recording increasing sales ... Zytiga's revenues will remain static in the short-term due to Xtandi taking market share and will begin to erode in the longer term as generic competition is expected." *Id.* at 2 .
	"Xtandi competes directly with Johnson & Johnson's (JNJ) Zytiga. It surpassed the drug in terms of sales. With the continued growth of the overall NHT market and Xtandi's increasing market share along with additional indications, the drug would have an addressable market of over $15 billion in sales." RJN, Ex. JJ at 2 (news article).
SAC ¶ 84(d): "Defendants willfully withheld Xtandi's relevant FDA approval dates to the Patent Office."	"The U.S. Food and Drug Administration today approved Xtandi (enzalutamide) to treat men with late-stage (metastatic) castration-resistant prostate cancer that has spread or recurred, even with medical or surgical therapy to minimize testosterone." RJN, Ex. C at 41 (June 4, 2013 Submission for '340 Application). "Approved for prostate cancer patients previously treated with docetaxel, another anti-cancer treatment, Xtandi was reviewed under the FDA's priority review program ... Xtandi received FDA approval three months ahead of the product's prescription drug user fee goal date of Nov. 22, 2012." *Id.*
	"The FDA has expanded the approval for enzalutamide (Xtandi) to include the treatment of men with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC), based on survival data from the phase III PREVAIL trial." RJN, Ex. T at 1 (journal article).
	"The FDA today approved enzalutamide for patients with metastatic castration-resistant prostate cancer that has spread or recurred, despite medical or surgical therapy to reduce testosterone. Approved for prostate cancer patients previously treated with docetaxel, enzalutamide (Xtandi, Medivation Inc.) was reviewed under the FDA's priority review program." RJN, Ex. U at 1 (journal article).

Relator's Allegations	Prior Public Disclosure
SAC ¶ 84(e): Defendants' description of market share based on patient-share data rather than direct sales was fraudulent and misleading because "patients suffering from prostate cancer often take many drugs" and "mCRPC patients typically build a tolerance to one drug, and move to another."	"Overall US Patient Share Continues to Grow" RJN, Ex. C at 58 (June 4, 2013 Submission for '340 Application). "The need for additional treatment options for advanced prostate cancer continues to be important for patients." *Id.* at 41. "Drugs, surgery or other hormones are used to reduce testosterone production or to block it. Some men have hormone refractory prostate cancer, meaning the prostate cancer cells continue to grow, despite testosterone suppression. Different treatments are needed for men with this type of cancer." *Id.* at 43.
	"[S]ome individuals administered current hormone therapy treatments may not show a significant response or may not show any response at all to such treatments. Additionally, some patients treated with current hormone therapy treatments may also suffer from relapsing or recurring cancer. Currently, such refractory cancer patients are left with very few treatment options." RJN, Ex. I at 2 ('340 Application Claim Specification). "[T]here is a need for effective anti-cancer treatment options for patients who are not responding to current anti-cancer treatments. Also, there is a need for effective anti-cancer treatment options for patients whose cancer has recurred." *Id.*
	"[P]atients will usually experience disease progression during or after docetaxel treatment due to inherent or acquired resistance." RJN, Ex. V at 170-71 (journal article).
	"One of the major challenges we face in treatment of mCRPC is that resistance to abiraterone and enzalutamide typically develops after 11 to 18 months of beginning therapy … In patients who are on abiraterone or enzalutamide therapy, and develop resistance but do not have significant symptoms, it's often possible to switch the patient to another of these androgen-receptor targeted drugs." RJN, Ex. KK at 16, 18 (scientific publication).
SAC ¶ 87(a): Defendants should have disclosed that other non-oral cancer drugs "have been far more successful than Zytiga."	Zytiga "was the second most successful oncology drug launch in U.S. history behind only Roche's Avastin." (Avastin is a non-oral drug). RJN, Ex. II at 1 (business article).

Relator's Allegations	Prior Public Disclosure
SAC ¶ 87(b)-(i): Defendants failed to demonstrate a nexus between Zytiga's commercial success and the claimed invention.	"Applicants did not offer relevant evidence of commercial success and the examiner issued the '438 patent based on the erroneous conclusion that the asserted commercial success of Zytiga overcame the obviousness of the claimed invention." RJN, Ex. D at 129-30 (Amerigen IPR Petition). "Applicants presented no evidence to suggest that the claimed invention, rather than the prior art abiraterone acetate was responsible for any commercial success of Zytiga." *Id.* at 130. "Zytiga's commercial performance, regardless of how broadly the relevant therapeutic market is defined, has been strong, any commercial success of Zytiga is not shown to derive from the claimed invention, i.e., the combination of abiraterone acetate and prednisone. Certainly, Applicants made no effort during prosecution to show any nexus between the claimed invention and the commercial performance of Zytiga. Instead, any commercial success of Zytiga is likely due to the effectiveness of abiraterone acetate in treating prostate cancer." *Id.* "[A]ny commercial success of Zytiga is likely due to the effectiveness of abiraterone acetate in treating prostate cancer." *Id.* "[E]ven assuming that the market definition Applicants used is accurate (and it is not), or that Applicants put Zytiga in the proper market context (which they did not), this information is insufficient as a matter of law because it fails to show any nexus between the claimed combination and the commercial performance of Zytiga." *Id.* at 205-06.
	"Even assuming that Zytiga's commercial performance has been strong, regardless of how broadly the relevant therapeutic market is defined, any commercial success of Zytiga has not been shown to derive from the claimed invention, i.e., the combination of abiraterone acetate and prednisone. Certainly, Applicants made no effort during prosecution of the '438 patent to show any nexus between the claimed invention and the commercial success of Zytiga." RJN, Ex. E at 206 (Mylan IPR Petition). "Examiner's allowance of the claims based on secondary considerations of commercial success of Zytiga was in error because Applicants failed to show the necessary nexus between the claimed invention (which is directed to a method of treating prostate cancer by administering abiraterone acetate and prednisone) and any commercial success of the drug Zytiga." *Id.* at 159. "Applicants made no effort during prosecution of the '438 patent to show any nexus between the claimed invention and the commercial success of Zytiga. Instead, any commercial success of Zytiga is likely due to the effectiveness of abiraterone acetate, in isolation, in treating prostate cancer." *Id.* at 206. "[A]ny commercial success of Zytiga has not been shown to derive from the claimed invention, i.e., the combination of abiraterone acetate and prednisone." *Id.*

Relator's Allegations	Prior Public Disclosure
	"There is no nexus between the performance of Zytiga and the '438 patent claims because any features of the '438 patent driving Zytiga's sales already existed in the prior art." RJN, Ex. F at 290-92 (Wockhardt IPR Petition). "Janssen has failed to provide any evidence [of] nexus between the Zytiga sales and the '438 patent, either during prosecution or in the 286 POPR." *Id.* at 290. "[S]everal factors demonstrate a lack of nexus between the '438 patent claims and Zytiga's performance: (1) the '438 patent cannot claim invention of the abiraterone or prednisone compounds themselves; (2) both abiraterone and prednisone were well-known in the prior art, as was administering prednisone with other anti-cancer agents, including CYP17 inhibitors; and (3) the lack of evidence that Zytiga's sales are driven by the benefits of adding prednisone to the treatment of abiraterone acetate." *Id.*
SAC ¶ 87(b): Defendants should have disclosed that "[a]ll drugs for treating mCRPC have short efficacy periods because the disease quickly becomes resistant to a given drug," thus patients "frequently switch medications" and "any new CRPC drug is likely to have some immediate commercial success."	"Drugs, surgery or other hormones are used to reduce testosterone production or to block it. Some men have hormone refractory prostate cancer, meaning the prostate cancer cells continue to grow, despite testosterone suppression. Different treatments are needed for men with this type of cancer." RJN, Ex. C at 43 (June 4, 2013 Submission for '340 Application).
	"[A]ny commercial success of Zytiga is likely due to the effectiveness of abiraterone acetate in treating prostate cancer." RJN, Ex. D at 130 (Amerigen IPR Petition).
	"[A]ny commercial success of Zytiga is likely due to the effectiveness of abiraterone acetate, in isolation, in treating prostate cancer." RJN, Ex. E at 206 (Mylan IPR Petition).
	"Janssen cannot show non-obviousness if Zytiga's alleged commercial success is attributable to characteristics of the claimed method that were already in the prior art." RJN, Ex. F at 290 (Wockhardt IPR Petition).
	"The majority of these deaths are caused by prostate cancer that becomes resistant to initial therapy and spreads to other sites, called metastatic castration-resistant prostate cancer ... Castration-resistant prostate cancer is more difficult to treat and cure because scientists are unsure how it develops resistance to anti-androgen therapies." RJN, Ex. W at 1 (scientific article).
	"75% to 85% of patients respond to abiraterone or enzalutamide initially, but a subsequent PSA increase or tumor progression occurs in nearly all of them with time. In the first-line CRPC setting, resistance typically develops after 9 to 15 months of treatment with either agent." RJN, Ex. X at 1 (scientific article). "Primary resistance is difficult to prevent, but a number of different approaches attempting to delay acquired resistance are being studied." *Id.* at 3.
	"[M]ost prostate cancer acquires resistance to the initial hormonal therapy over approximately 2–3 years, thus progressing to CRPC." RJN, Ex. Z at 2-3 (scientific article).

Relator's Allegations	Prior Public Disclosure
SAC ¶ 87(c): Defendants should have disclosed that Zytiga enjoyed a commercial advantage over Xtandi because "Zytiga was approved and launched first" and "it does not sequence well with its biggest competitor in the chemo refractory mCRPC market, Xtandi."	Discussing findings that "clearly show[ ] that cross-resistance occurs between enzalutamide and abiraterone." RJN, Ex. X at 1 (scientific article).
	"The abiraterone-to-enzalutamide sequence might have more favorable efficacy in terms of combined prostate-specific antigen progression-free survival than the enzalutamide-to-abiraterone sequence, although no differences in overall survival were observed. This could possibly be attributable to longer prostate-specific antigen progression-free survival with second-line enzalutamide compared with abiraterone." RJN, Ex. Z at 2, 11-13 (scientific article).
SAC ¶ 87(d): Defendants should have disclosed that "Zytiga was recommended in some cases because it was the least toxic."	"Abiraterone + prednisone and enzalutamide have clinical benefit and may be administered with significantly less acute toxicity and no apparent cumulative toxicity as compared to approved chemotherapy in this clinical scenario." RJN, Ex. G at 434 (scientific publication) (article also expressly cited in SAC ¶ 87(d)). "Because of the need for intravenous administration, the more modest clinical benefit and the higher rates of significant toxicity, cabazitaxel is ranked below abiraterone + prednisone and enzalutamide for this group of patients." *Id.* at 435.
	"In men with asymptomatic or minimally symptomatic metastatic CRPC, abiraterone is an attractive first-line option given its ease of administration and relatively low toxicity profile." RJN, Ex. O at 46 (scientific article) (article also submitted in connection with '340 Application).
	"Since the 1940s, hormone therapy has been the standard treatment for men with advanced prostate cancer ... Cancer doctors have followed this tactic because hormone therapy is less toxic and has fewer side effects than chemotherapy." RJN, Ex. AA at 1 (scientific article).

Relator's Allegations	Prior Public Disclosure
SAC ¶ 87(e): The '213 Patent "blocked" the commercial development of abiraterone, which "casts substantial doubt" on Zytiga's sales success. This "blocking patent" was not disclosed to the USPTO.	"The '213 patent is incorporated by reference in the '438 patent, but it was neither argued nor disclosed in an IDS as relevant prior art during prosecution." RJN, Ex. D at 113 (Amerigen IPR Petition). "The '213 is a blocking patent that limits the applicability of commercial success" *Id.* at 136-38. "Because the '213 patent claims abiraterone acetate and its use in a method of treating an androgen-dependent disorder, 'no entity other than' the patentee 'could have successfully brought [abiraterone acetate] to market.' The ability of the patentees of the '213 to block additional research and development of abiraterone acetate limits the relevance of commercial success for the '438 patent." *Id.* at 137. "[T]he '213 patent was a blocking patent that limited economic incentives to develop the invention of the '438 patent. As Dr. McDuff explains, 'Because Johnson & Johnson could have effectively prevented market participants from supplying an abiraterone product, typical incentives associated with drug development would not have existed.'" *Id.* at 137-38.
	"[T]he '213 patent is incorporated by reference in the '438 patent, but the '213 patent was neither argued nor disclosed to the PTO in an IDS during prosecution of the '438 patent." RJN, Ex. E at 188 (Mylan IPR Petition). "The '213 is a blocking patent that limits the applicability of commercial success." *Id.* at 212-14. "Because the '213 patent claims abiraterone acetate and its use in a method of treating an androgen-dependent disorder, 'no entity other than' the patentee 'could have successfully brought [abiraterone acetate] to market.' The ability of the patentees of the '213 to block additional research and development of abiraterone acetate limits the relevance of commercial success for the '438 patent." *Id.* at 213. "[T]he '213 patent was a blocking patent that limited economic incentives to develop the invention of the '438 patent. As Dr. Hoffmann explains, 'the existence of the '213 Patent prevents the performance of Zytiga from providing objective evidence of nonobviousness of the '438 Patent.'" *Id.* at 214.
	"Patent-based and FDA-based exclusivities limit any economic relevance of commercial success." RJN, Ex. F at 286-89 (Amerigen IPR Petition). "The evidence shows, as discussed in Dr. Stoner's declaration, that Zytiga's success, if any, derives from a blocking patent—separate from the '438 patent here—and the New Chemical Entity ("NCE") FDA regulatory exclusivity, both of which serve to preclude competition resulting in higher sales of Zytiga." *Id.* at 286. "Janssen has enjoyed the blocking exclusivity of U.S. Patent No. 5,604,213, which claims that abiraterone compound and methods for treating an androgen-dependent disorders (such as prostate cancer) using abiraterone and abiraterone acetate. The '213 patent issued in 1997, over 19 years ago, and will not expire until December 2016. Similarly, Janssen has enjoyed five years of marketing NCE exclusivity for abiraterone acetate since April 2011 for Zytiga. These patent and statutory blocks are what's responsible for Zytiga's sales; not the '438 patent." *Id.* at 287. "'[B]locking patent' activity of the '213 patent limits the relevance of analysis of commercial success as it relates to the '438 Patent." *Id.* at 288.

Relator's Allegations	Prior Public Disclosure
	"17a-hydroxylase/C17,20-lyase inhibitors have been shown to be useful in the treatment of cancer, specifically hormone-dependent disorders such as, androgen-dependent and estrogen-dependent disorders like prostate cancer and breast cancer respectively, as described in United States Patent No. 5,604,213 to Barrie et al., which is herein incorporated by reference in its entirety." RJN, Ex. I at 7 ('340 Application Claim Specification). "'The 17a-hydroxylase/C17,20-lyase inhibitors can be made according to any method known to one skilled in the art. For example, such inhibitors can be synthesized according to the method disclosed in United State Patent Nos 5,604,213 and 5,618,807 to Barrie et al., herein incorporated by reference." *Id.* at 10.
	"Three years after the initial approval of branded Zytiga (abiraterone acetate), the manufacturer of Zytiga received approval for an additional patent, which will extend the period of exclusivity beyond that of the composition-of-matter patent." RJN, Ex. S at S492-93 (scientific publication).
SAC ¶ 87(f): Defendants should have disclosed that mCRPC drugs "usually extend a patient's life by a few months, at best" and therefore "alleviating side effects may not have actually been a factor in the decision to prescribe or take Zytiga as of 2013."	Study of safety and effectiveness of Xtandi "was designed to measure overall survival (the length of time before death) in men receiving Xtandi compared with men receiving a placebo (sugar pill). The median overall survival for patients receiving Xtandi was 18.4 months, compared with 13.6 months for the patients who received placebo." RJN, Ex. C at 41 (June 4, 2013 Submission for '340 Application). "The median overall survival for patients receiving Jevtana regimen was 15.1 months compared with 12.7 months for those who received the mitoxantrone regimen." *Id.* at 43. "Patients who received Zytiga had a median overall survival of 35.3 months compared with 30.1 months for those receiving the placebo." *Id.* at 45.
	"[T]he expansion of Zytiga's label to include an indication for treating pre-chemo patients due to data that 'showed that Zytiga plus prednisone provides a statistically significant overall survival benefit vs. prednisone alone' failed to have any market effect." RJN, Ex. F at 292 (Wockhardt IPR Petition). "[S]everal factors demonstrate a lack of nexus between the '438 patent claims and Zytiga's performance: (1) the '438 patent cannot claim invention of the abiraterone or prednisone compounds themselves; (2) both abiraterone and prednisone were well-known in the prior art, as was administering prednisone with other anti-cancer agents, including CYP17 inhibitors; and (3) the lack of evidence that Zytiga's sales are driven by the benefits of adding prednisone to the treatment of abiraterone acetate." *Id.*
	"The Food and Drug Administration approved a new life-prolonging drug for men with late-stage prostate cancer on Friday . . . In clinical trials, men who received the drug, which was previously known as MDV3100, lived a median of 18.4 months, nearly five months longer than the median of 13.6 months of those who received a placebo." RJN, Ex. Y at 1 (news article). "Zytiga prolonged median survival by 3.9 months, as initially reported, though Johnson & Johnson later updated that figure to 4.6 months." *Id.* at 2.

Relator's Allegations	Prior Public Disclosure
SAC ¶ 87(g): Defendants should have disclosed that "Zytiga is an oral medication, whereas Jevtana is a one-hour intravenous infusion" and "Zytiga's commercial success compared to Jevtana related to different routes of administration."	"Because of the need for intravenous administration, the more modest clinical benefit and the higher rates of significant toxicity, cabazitaxel **[Jevtana]** is ranked below abiraterone + prednisone and enzalutamide for this group of patients." RJN, Ex. G at 435 (scientific publication) (article expressly cited in SAC ¶ 87(d)).
	"In men with asymptomatic or minimally symptomatic metastatic CRPC, abiraterone is an attractive first-line option given its ease of administration and relatively low toxicity profile." RJN, Ex. O at 46 (scientific article) (article also submitted in connection with '340 Application).
	"Oral formulations can be favourable over injections and infusions that require healthcare facility visits." RJN, Ex. R at 3 (business article).
	Zytiga is an "oral, once-daily" "prescription medication that is used along with prednisone." RJN, Ex. DD at 2, 4 (Zytiga webpage).
	"Swallow Xtandi capsules whole." RJN, Ex. EE at 1 (Xtandi webpage).
	"Jevtana is an infusion medicine." RJN, Ex. FF at 1 (Jevtana webpage).
	"Zytiga tablets should be swallowed whole with water." RJN, Ex. LL at 1 (scientific article).
	"Xtandi, an androgen receptor inhibitor, is taken orally, once a day." RJN, Ex. MM at 2 (scientific article).
	"Sanofi sells Cabazitaxel injection under brand name Jevtana." RJN, Ex. NN at 2 (news article).
SAC ¶ 87(b): Defendants should have disclosed that "the price of Zytiga was considerably less than Xtandi and Jevtana."	"Zytiga costs $5,500 a month, while Xtandi gets $7,450 a month." RJN, Ex. BB at 3 (news article).
	Jevtana "costs about $8,000 every three weeks." RJN, Ex. CC at 2 (news article).
SAC ¶ 117: "Defendants implicitly certified that that the average manufacturer price reported had not been unlawfully inflated through the exclusion of competitors" but "the prices they negotiated with the government for Zytiga were based on illegally-obtained patent protection, and thus manifestly were not 'fair and reasonable.'"	"VA awards contracts to responsible companies offering commercial items at fair and reasonable prices. Contracting Officers determine whether prices are fair and reasonable by comparing the prices/discounts that a company offers the government with the prices/discounts offered to commercial customers" RJN, Ex. H at CP-8 (GSA Solicitation Document). "The goal of this review process is to ensure the vendor is responsible, the Government is receiving a fair and reasonable price, and that any potential contract award is in the interest of the Government." *Id.* at CP-11.
	disclosing price of Zytiga and existence of 2011 FSS contract RJN, Ex. GG at 1 (FSS for Zytiga 250MG Tablet); RJN, Ex. HH at 1 (FSS for Zytiga 500MG Tablet)..
	See public disclosure of IPRs contesting patent validity and other underlying alleged transactions, *supra*.